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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/813,315

03/30/2004

Ramesh Babu Jayaraman

TRTC-0003

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EXAMINER

KENNEDY, SHARON E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/813,315	Applicant(s) JAYARAMAN ET AL.	
	Examiner Sharon E. Kennedy	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) 6-10, 12-14 and 41-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11 and 15-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/12/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on February 4, 2008 is acknowledged. The traversal is on the ground(s) that there is no burden on the examiner to search both groups I and III since they are placed in the same classification schedule. This is not found persuasive because claims 85-87 are directed to a different type of implant. However, claim 1 is considered to be a linking claim. Claims 41 and 42 will be rejoined in the event that they are dependent upon allowable subject matter found in claim 1. Similarly, claims 6-10, 12-14 will also be rejoined.

However, at this time, claims 6-10, 12-14, 41-96 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 11, 15-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for the example of Thoralon^R coating, does not reasonably provide enablement for any siloxane modified polyetherurethane polymer. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant discloses two patents useful for the polyetherurethane polymer modified by the siloxane in paragraph [0023], however, these patents disclose numerous polymer combinations and one of ordinary skill in the art would not be able to make and use an operable invention without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11, 31-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jayaraman et al., US 2002/0065552. Jayaraman discloses vascular grafts coated with Thoralon^R (see Abstract) which may also be used to deliver therapeutics [0024].

Claims 1, 11, 31-33 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Holloway et al., US 6,752,826. Holloway discloses a stent-graft having a

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porous outer layer 12 which may be Thoralon^R and which may delivery therapeutics (column 4, line 64 to column 5, line 19; column 10, lines 62+). The other layers may comprise Thoralon^R as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5, 15-30, 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holloway '826. Regarding claims 2-5, 37-39, applicant claims various loading areas for the stent. Holloway discloses multiple layers each which may be a drug delivery layer. It would be obvious to one of ordinary skill in the art to load one drug in one layer and another drug in a second layer to avoid incompatibility issues, for example, or encourage drug delivery to preferred locations. Regarding claims directed to coating part of the stent and not others, it is obvious to one of ordinary skill in the art to eliminate drug in a location on a medical device where it is not wanted to save costs, for example. Claims 15-30 recited various loading formulae for the drug. Holloway does not detail the loading or the specific drugs, but states that any drug may be useful, particularly antiproliferatives, anti-adhesion, etc. Applicant's specification has been carefully reviewed for an indication that the various loading parameters are critical or unexpected, however, nothing is emphasized. Accordingly, the examiner takes the

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position that the loading ranges are obvious to one of ordinary skill in the art using routine experimentation. See MPEP 2144.05, II., entitled "Optimization of Ranges." [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holloway as applied to claim 1 above, and further in view of Falotico et al, US 2002/0016625. Holloway discloses that the drugs loaded onto the stent graft may comprise antiproliferatives, etc., Falotico is cited to exemplify that stents loaded with rapamycin and/or paclitaxol is well known in the art. It would be obvious to one of ordinary skill in the art to use the classic antiproliferatives drugs in the Holloway stent since Holloway specifically suggests these types of drugs.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sharon E. Kennedy/

Sharon E. Kennedy
Primary Examiner
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